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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/850,991	05/08/2001	Jens Kossmann	GFB-7 DIV	3510

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EXAMINER	
FOX, DAVID T	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/850,991	Kossman et al
Examiner	**Group Art Unit**
Fox	1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Peri d for Reply

-3-

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 10/16/02.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disp sition of Claims

☑ Claim(s) 1, 16, 22-26, 28, 34-35 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1, 16, 22-26, 28, 34-35 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Applicati n Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☑ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☑ received in Application No. (Series Code/Serial Number) 09/148,680.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 1 1/2

☐ Interview Summary, PTO-413

☑ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

Applicant's election without traverse of Group I in Paper No. 6 is acknowledged. All remaining claims are drawn to the elected group.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 16, 22-24 and 28 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 16 and 22-24 are drawn to plant cells comprising a native maize gene encoding debranching enzyme Thus, the claims read on naturally occurring maize cells and plants containing them. Claim 28 is drawn to propagation material of transgenic plants, which encompasses seeds. Given the loss of one half of the genetic complement at every locus due to meiosis, the transgene would be lost in some of the seeds, and the seeds would be indistinguishable from naturally occurring seeds. Thus, the claims are drawn to products of nature.

See *American Wood v. Fiber Distintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

The following amendments would obviate this rejection:

Amend claim 16 as follows:

--Claim 16 (amended). A host cell [comprising] transformed with the nucleic acid molecule of claim 1, or a host cell comprising a vector comprising the nucleic acid molecule of claim 1.--

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 16, 22-26, 28 and 34-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in the rejections.

Claim 1 is indefinite in its recitation of "when introduced in antisense orientation" as it is unclear whether the isolated nucleic acid molecule is actually in antisense orientation with respect to a promoter, or whether this is merely a recitation of an intended use. Thus, the claim does not positively recite required claim elements. Furthermore, the failure to recite other claim elements, to which the orientation of the nucleic acid molecule can be compared, renders "antisense orientation" meaningless. The following amendment would obviate this rejection:

In claim 1, line 1, insert --a promoter operably linked to-- after "comprising".

In claim 1, line 2, insert --in antisense orientation thereto-- after the first recitation of "sequence".

In claim 1, last line, insert --with respect to the promoter-- before the period.

Claims 22 and 34 are indefinite in their recitation of "has a sequence identity of more than 95%" as it is unclear to which sequence the identity is calculated. The following amendments would obviate this rejection:

In claims 22 and 34, line 2, delete "of (d)" before "has", and insert --to (a) or (b)-- before the period.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 16, 24-26 and 28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to isolated nucleic acid molecules comprising a multitude of nucleic acid sequences or parts thereof which hybridize under conditions of unspecified stringency to the exemplified sequences, and host cells containing them. In contrast, the specification only demonstrates the obention of the native maize gene encoding native debranching enyzme, and methods for its use. No guidance is provided for the obtention or characterization of the multitude of non-exemplified sequences from non-exemplified sources, which sequences (or a multitude of parts thereof) would hybridize to the exemplified gene under conditions of low or moderate stringency.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California* v. *Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

Claims 1, 16, 24-26 and 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to an isolated nucleic acid molecule comprising a plant promoter operably linked to a part of a nucleic acid sequence, which nucleic

acid sequence is at least 90% identical to SEQ ID NO:1 or to a sequence encoding SEQ ID NO:2, wherein said part is sufficient to inhibit debranching enzyme activity when introduced in antisense orientation; does not reasonably provide enablement for claims broadly drawn to an isolated nucleic acid molecule comprising a multitude of nucleic acid sequences which hybridize thereto under conditions of low or moderate stringency or a multitude of parts thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to isolated nucleic acid molecules comprising a multitude of nucleic acid sequences or parts thereof which hybridize under conditions of unspecified stringency to the exemplified maize sequences encoding debranching enzyme, wherein said nucleic acid sequences are operably linked to a promoter in antisense orientation, and host cells containing them. In contrast, the specification only demonstrates the obention of the native maize gene encoding native debranching enyzme, and methods for its use. No guidance is provided for the obtention or characterization of the multitude of non-exemplified sequences from non-exemplified sources, which sequences (or a multitude of parts thereof) would hybridize to the exemplified gene under conditions of low or moderate stringency.

The process of modifying starch accumulation or degree of branching in transgenic plants via antisense RNA is particularly unpredictable. See Kossmann et al (1995; Progress in Biotechnology, Volume 10), who teach the lack of influence of antisense potato starch

accumulation genes on branching or phosphate content of starch (page 275, third through fifth full paragraphs), the difficulty inherent in isolating individual starch synthesis enzymes or their corresponding genes (paragraph bridging pages 275 and 276), and the lack of correlation between reduction of branching enzyme gene activity and branching of starch in transgenic plants (see, e.g., page 277, penultimate paragraph). See also Willmitzer et al, page 38, third full paragraph, who teach the failure of an antisense branching enzyme gene to alter the degree of starch produced in transformed potato plants, despite the virtually complete inhibition of branching enzyme activity.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to isolate and evaluate a multitude of non-exemplified sequences or parts thereof, hybridizing to the maize debranching enzyme gene under conditions of low or moderate stringency, for their ability to inhibit debranching enzyme activity and/or effect any phenotypic change in starch branching or accumulation in transgenic plants.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16, 22-24 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Black et al.

The claims are broadly drawn to maize cells and propagation material which contain the native maize debranching enzyme gene, as discussed above.

Black et al teach maize kernels (propagation material) comprising maize cells (see, e.g., page 662, top paragraph), wherein said maize cells and kernels would inherently contain the native maize debranching enzyme genes. Amendment of the claims to overcome the rejection under 35 USC 101 would obviate this rejection.

Claims 16, 22-24 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Doehlert et al.

The claims are broadly drawn to maize cells and propagation material which contain the native maize debranching enzyme gene, as discussed above.

Doehlert et al teach maize kernels (propagation material) comprising maize cells which comprise debranching enzymes (see, e.g., page 566, Abstract), wherein said maize cells and kernels would inherently contain the native maize debranching enzyme genes. Amendment of the claims to overcome the rejection under 35 USC 101 would obviate this rejection.

Claims 16, 22-26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Gordon-Kamm et al.

Claims 25-26 are broadly drawn to transgenic maize plants with an unspecified transgene, which plants also contain the native debranching enzyme genes, given the recitation that they merely comprise the plant cell of claim 24.

Gordon-Kamm et al teach transformed maize plants and progeny (see, e.g., page 603, Abstract), which progeny are inherently produced from seeds, and which plants and progeny would inherently contain the native maize debranching enzyme gene.

Amendment of claim 16 to overcome the rejection under 35 USC 101 would obviate this rejection.

Claims 1 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/09922 (MILLER BREWING).

The claims are broadly drawn to host cells which contain a part of an isolated nucleic acid molecule comprising a nucleic acid sequence which hybridizes to a maize debranching enzyme gene under conditions of unspecified stringency, wherein the part is of sufficient length to reduce the expression of a debranching enzyme gene if it were to be introduced into a plant cell in antisense orientation.

MILLER BREWING teaches an isolated pullulanase (debranching enzyme) gene which would inherently hybridize under conditions of low stringency to the maize debranching enzyme, and transformed microbial cells containing it (see, e.g., Abstract and claims 1-13).

Deletion of part (c) of claim 1 would obviate this rejection.

Claims 1 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by James et al.

The claims are broadly drawn to host cells which contain a part of an isolated nucleic acid molecule comprising a nucleic acid sequence which hybridizes to a maize debranching enzyme gene under conditions of unspecified stringency, wherein the part is of sufficient length to reduce the expression of a debranching enzyme gene if it were to be introduced into a plant cell in antisense orientation.

James et al teach an isolated debranching enzyme gene from maize which would inherently hybridize under conditions of at least low or moderate stringency to the claimed maize debranching enzyme gene, and transformed microbial cells containing it (see, e.g., page 417, Abstract; page 418, column 2, penultimate paragraph; page 420, paragraph bridging the columns).

Deletion of part (c) of claim 1 would obviate this rejection.

Claims 1, 16, 24-26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/03515 (MONSANTO).

The claims are broadly drawn to transformed plant cells and plants which contain a part of an isolated nucleic acid molecule comprising a nucleic acid sequence which hybridizes to a maize debranching enzyme gene under conditions of unspecified stringency, wherein the part is of sufficient length to reduce the expression of a debranching enzyme gene if it were to be introduced into a plant cell in antisense orientation.

MONSANTO teaches maize plant cells and plants transformed with an isolated isoamylase (debranching enzyme) gene (see, e.g., Abstract and claims 1-15, 17-22 and 25-27), wherein the

gene would inherently hybridize under conditions of low stringency to the maize debranching enzyme gene. The gene would inherently reduce debranching enzyme gene expression if it were to be introduced into a plant cell in antisense orientation.

Amendment of claim 1 to delete part (c) and otherwise clarify the requirement for antisense orientation would obviate this rejection.

Isolated nucleic acid molecules comprising SEQ ID NO:1 or encoding SEQ ID NO:2, or isolated nucleic acid molecules at least 90% identical thereto, each in sense orientation, were deemed free of the prior art and allowable in the parent application serial no. 09/148,680, now U.S. Patent 6,255,561.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

January 2, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~1800~~ 1638